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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,422	01/10/2002	Kazumitsu Nakatsuka	21 7962US0PCT	5990
22850 7590 04/09/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/09/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/030,422	NAKATSUKA, KAZUMITSU	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-19,21,25,26 and 28-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-19,21,25,26 and 28-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt request for extension of time, IDS, amendment and remarks, all filed 12/12/05. Claims 7, 13, 28 and 34 are amended. Claims 7-19, 21, 25, 26 and 29-43 are pending. The amendment to the claims now requires that the pH be at 1.5 to 5.5.

Rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 7-19, 21, 25, 26 and 29-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imazato et al. (US 5,733,940) in view of Kelm et al. (US 5,646,174) and further in view of Boggs et al. (US 5,286,480).

Imazato provides an antimicrobial dental composition comprising an antimicrobial polymerizable monomer, a polymerizable monomer having acidic group, a polymerizable monomer having alcoholic hydroxy group, water and a polymerization catalyst (column 2, lines 27-34) and discloses that the composition may be mixed with dental acrylic adhesive comprising polymerizable monomer of acrylic base and polymerization initiator (column 6, line 66 to col. 7, line 27,). Imazato also discloses pyridinium antimicrobial agent and the antimicrobial

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pyridinium has polymerizable group. Imazato discloses 12-methacryloxydodecylpyridiniumbromide (MDPB) having the chemical structure shown in Formula 4 as the antimicrobial polymerizable monomer used in the invention (Examples 1-24 and claim 5). MDPB is an antibacterial polymerizable pyridinium salt compound, as claimed by Applicant.

With regard to the polymerizable monomer having acidic group (b) claimed in claim 7 of the instant application, the patent discloses polymerizable monomers having acidic group, such as phosphoric acid, carboxylic acid or sulfonic acid group, and includes methacryloyloxydecyl dihydrogen phosphate (MDP) among said polymerizable monomers (column 5, lines 20-60 and Examples 5-12).

With respect to the hydrophilic polymerizable monomer (c) claimed in claim 7 of the instant application, the patent discloses polymerizable monomers having alcoholic hydroxy group, and includes 2-hydroxyethyl methacrylate (HEMA) among said monomers (column 5, line 61 to column 6, line 11 and Examples 1-8). The polymerizable monomers having alcoholic hydroxy group disclosed by the Imazato, and specifically HEMA, are hydrophilic polymerizable monomers, as claimed by Applicant. With respect to the water (d) claimed in claim 7 of the instant application, Imazato provides water substantially free of impurities in the composition of the invention (See col. 6, lines 12-21).

Kelm teaches a dental treatment composition (column 3, lines 23-28; column 5, lines 8-15, 36) that comprises antimicrobial agents such as pyridinium salts (column 7, line 62 to column 8 line 11), bases such as trimethylamine, diethylamine, ethanolamine (column 3, lines 47-67) with the pH of the composition maintained at from about 2 to 9 (column 4, lines 55-58)

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and buffereing agents such as phosphate salts such as dibasic or monobasic phosphates (column 6, lines 66 and 67; Examples 3, 4, 6 and 7 for a teaching of the use of phosphates).

Boggs teaches dental treatment composition (column 2, lines 2 and 3; column 4, lines 46-50) comprising antimicrobial agent such as pyridinium salts (column 7, lines 26-30) and sodium hydroxide and the pH of the composition is maintained at form about 3 to about 7 (column 8, lines 43-46).

Imazato is silent on the pH of the composition, while the pH of the antimicrobial dental treatment compositions of Kelm and Boggs is from about 2 to about 9 and from about 3 to about 7 respectively meeting the pH requirement of claims 7 and 28. The presence of sodium hydroxide in the antimicrobial composition Boggs meets the requirements of claims 7, 11, 12, 32 and 33. The presence of phosphates and amines in the composition of Kelm further meets the requirements of claims 13-18, 28 and 34-39. Imazato's polymerization catalysts are peroxides, tertiary amines and quinine derivatives (column 6, lines 24-38) meeting the requirements of claims 21 and 41. Claims 25, 26, 42 and 43 are characteristic/properties of the antimicrobial compositions and the composition derived from the combined teachings of Imazato, Kelm and Boggs would inherently have that characteristic/properties. The MDPB of Imazato (column 9, lines 13 and 14) is a polymerization pyridinium salt meeting claims 8-10 and 29-31 and the acrylates meet claims 19 and 40.

Imazato is silent on the pH of the antimicrobial composition, which is indicative that any pH would be suitable. Kelm and Boggs teach that the pH of the antimicrobial composition could be from about 2 to about 9 and form about 3 to about 7 respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching

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of Imazato to prepare and apply the anti-microbial dental treatment composition to teeth. It would have been obvious to modify the composition taught by Imazato to a pH of from about 2 to about 9, which overlaps the claimed pH range.

Response to Arguments

3. Applicant's arguments filed 12/28/06 have been fully considered but they are not persuasive.

Applicant argues that a) the composition of Imazoto does not have basic material and that example 9, which is the composition of Imazato did not completely kill the cells of *Streptococcus mutans* even at concentrations of 10% while the claimed invention in examples 6-9 even at concentrations of 5% completely killed the cells of *Streptococcus mutan*; b) also, the inventive composition does not discolor when stored at 50 °C for 1 month while the composition of Imazato discolors when stored at 50 °C for 1 month; c) Imazato does not provide suggestion or motivation to modify the disclosure to include basic component according to claims 7 and 18; d) examiner recognized the deficiency in Imazato and used Fisher to provide a teaching that NaOH can be used to adjust Ph of compositions to approximate the composition to physiological pH, and that the pH of Fisher from about 5 to about 7.

Response:

Regarding a), the examiner agrees with applicant that the composition of Imazato does not contain a base such as NaOH, and it for that reason that a rejection under 35 USC 103 was made with motivation to optimize the composition of Imazato by adjusting the pH to the physiological pH. This rejection was made when the claims did not claim any specific pH

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indicating the composition would function at least most or all pH values. However, the claims have been amended to recite specific pH range. Thus the data provided on Table 2 is not commensurate with the claims presented 12/11/05 without the claim to specific pH range. Secondly, the data on Table 2 generated from composition that contains 3% MDPB and over all concentration of 5% is not commensurate with the claims that are broadly directed to composition comprising at least one antimicrobial salt, at least one acid group having polymerizable monomer, water and at least one basic compound (see instant claims 7 and 28). However, the amendment to the claims where specific pH range is claimed changes the claims and gives rise to the rejections above.

Regarding b), applicant compares Imazato's composition before the modification with the inventive composition and in so doing applicant ignored the modification that would led to inventive composition.

Regarding c), the suggestion of motivation to modify comes from Imazato teaching a dental treatment composition that was designed to be applied to the teeth. Since the composition is to be applied to a subject having known physiological pH, it flows that the motivation was to make sure that the composition is at physiological pH.

Regarding d), Fisher was used as a teaching reference or a reference that provided the evidence that NaOH is used to adjust pH of dental treatment composition and such the Fisher pH was not relied upon as providing guidance as to what pH the composition may be adjusted to. It is also noted that the pH limitation was introduced in the amendment filed 12/28/06.

No claim is allowed.

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4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

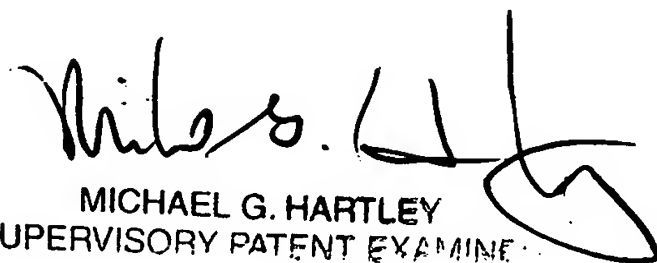
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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